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January 7, 1998

8EHQ-0198-14099

454400006B

Document Processing Center (TS-790)
Attention: (8e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Ladies and Gentlemen:

Subject:

Notice in Accordance to TSCA Section 8(e) - Results of an acute inhalation toxicity study in rats with Substituted Benzylether.

BASF Corporation is submitting the results of an acute inhalation study in Wistar rats conducted as a 4-hour liquid aerosol exposure. The study was conducted by our parent company, BASF Aktiengesellschaft, Ludwigshafen, Germany.

The test substance with the name Substituted Benzylether is a developmental fungicide. Small shipments totaling approximately 500 grams active ingredient have been shipped since November 1995.

The following results were obtained in the acute inhalation study:

For determination of the acute inhalation toxicity (single 4-hour exposure) of the test substance as a liquid aerosol, a study in male and female Wistar rats was performed according to OECD-Guideline method 403, as well as EEC and EPA guidelines. For technical reasons the substance was tested as solution in acetone and an acetone control group was exposed to a nominal concentration comparable to the high concentration of substance solution. The following concentrations were tested: acetone control; 0.31, 1.07 and 5.3 mg/l. No mortality occurred in the acetone control and at 0.31 mg/l. All animals died during exposure at 1.07 and 5.3 mg/l. The LC₅₀ was estimated to be 0.31 - 1.07 mg/l.

The particle size distributions revealed mass median aerodynamic diameters (MMADs) between 1.0 and 2.9 µm, which are in a well respirable range. Some changes in respiration pattern consistently occurred in all exposed groups, but concentration dependent specific clinical symptoms were not observed. All animals in the acetone group were without clinical findings from study day 1 onward. In the low concentration group, the animals were without clinical findings from study day 7 onward. Body weight development of the male animals exposed to acetone or the low concentration was not influenced, whereas it was slightly depressed in the females of both groups.

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During necropsy, the animals of the mid concentration group showed agonal congestive hyperemia, while that of the high concentration group showed no macroscopic abnormalities. No macroscopic pathologic findings were noted in the animals of acetone control and low concentration group which were examined at the end of the study.

Although these findings are not considered to present a substantial risk to health or environment, BASF Corporation understands that the reporting of these study results is in accordance with EPA's policy under TSCA Section 8(e).

All persons handling or testing this developmental product will be notified of these preliminary results via an updated Material Safety Data Sheet. Any reports or additional information that we receive will be forwarded to the Agency.

If you have any questions, please feel free to call me at (734) 324-6207.

Very Truly Yours,

BASF Corporation

Edward J. Kerfoot, Ph.D. Director, Toxicology and Product Regulations

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